REMARKS

Claims 35-48 and 50-56 are currently pending.

Claims 35-48 and 50-56 stand rejected under 35 USC 102(b) as being anticipated by or, in the alternative, under 35 USC 103(a) as obvious over Ketharanathan. This rejection is respectfully traversed.

The Examiner alleges that Ketharanathan discloses a method for fabricating a surgical graft, the method includes implanting a rod or tube in a host and growing a coherent tubular wall of collagenous tissue. The implant is then removed from the host and the collagenous tissue removed from the rod or tube, the tissue treated and used as a prosthesis. The Examiner alleges that while Ketharanathan does not recite myofibroblasts forming on the molding support, it is well known that myofibroblasts are precursors to collagen tissue. Applicants respectfully disagree with the Examiner.

Ketharanathan describes the generation of biosynthetic grafts generated by the following methods. Implants were constructed by stretching tubular polyester mesh over nylon cylinders or silastic rods. These rods were implanted beneath the cutaneous trunci muscle of the lateral thoracic wall and left in place for at least 12 weeks. The implants were then removed from the sheep and the biosynthetic tubes isolated. The composition of the biosynthetic tubes after removal from the sheep is not described by Ketharanathan. The composition was only evaluated after it was removed from the recipient (see column 4, lines 39-44). At this stage, the graft is allegedly composed of mature collagen with a smooth inner surface. Ketharanathan states that after functioning as a vascular implant for 257 days, the graft became lined with multiple layers of endothelium and the wall was reinforced with new collagen.

Accordingly, in Ketharanathan the rod or tube is placed beneath the cutaneous muscle of the lateral thoracic wall, which results in the rod or tube being in the body, not in a body cavity as required by the present invention. Further, the methods described in Ketharanathan result in a

graft which is composed of Type I collagenous tissue. This does not specifically relate to myofibroblasts, which synthesize both Type I and small amounts of Type III collagen. Indeed, given the location of the rods or tubes used in Ketharanathan, the implants are most probably formed by skin fibroblasts, which produce Type I collagen only.

In addition, the vascular grafts used in Ketharanathan are merely a tube of collagen. There are no living cells in it as they subject it to "glutaraldehyde tanning in order to produce cross-linking of collagen fibrils." (See Ketharanathan, claim 5 and col. 1, lines 34 and 35). The claimed grafts do not have cross-linked collagen, but rather collagen in its native form. Further, the tissue generated using the claimed methods is primarily composed of living myofibroblasts with collagens I and III, which are merely the extracellular glue holding the cells together.

The tissue grafts generated in Ketharanathan are left to grow for 10-12 weeks. In comparison, the grafts described in applicants' specification are only grown for 2-3 weeks, thereby ensuring, as claimed, that the tissues include myofibroblasts. If the grafts of the present invention were allowed to grow for 10-12 weeks, then they would *not* be composed of myofibroblasts. This is because it is avascular (i.e. has no blood supply) and the cells start to die after about three weeks when the tissue wall becomes thicker than about 1mm. Accordingly, the claimed graft must have living myofibroblasts as their presence results in an implant that is compliant and strong, and can repair damage to the wall by replicating and by fresh synthesis of collagens I and III. The implant described in Ketharanathan is dead, and therefore cannot repair itself and must rely upon cross-linking of the collagen I "so as to increase the strength of the wall and also to impart immunological inertness and sterility." (See Ketharanathan, claim 5).

Accordingly, the rejection of claims 35-48 and 50-56 as anticipated by or obvious in view of Ketharanathan should be withdrawn.

The Examiner has also rejected claims 40-43 and 53 for allegedly being obvious in light of Ketharanathan in view of Tranquillo, Sparks, Dardik, or Bruchman. These rejections are

respectfully traversed. As explained above, Ketharanathan fails to disclose the claimed method. Further, Tranquillo, Sparks, Dardik, and Bruchman fail to disclose or suggest methods for correcting the previously described defects Ketharanathan. Accordingly, these rejections of claims 40-43 and 53, should be withdrawn.

Favorable reconsideration and allowance of the currently pending claims is respectfully solicited.

In the event the Patent and Trademark Office determines that an extension and/or other relief is required, applicants petition for any required relief including extensions of time and authorize the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing Attorney Docket No. **229752001220**.

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